

1. Project evaluation before Directive 2010/63/EU

According to the FELASA Report (2005, p. 10), the ethical review was mandatory and there was a National Committee since 2006. Before 2006 the committees were institutional and some were shared between institutions.

2. Implementation of Directive 2010/63/EU

The directive is transposed into national law (since 01.08.2013) through

- Act on the Protection of Animals used for Scientific or Educational Purposes (497/2013, available at: <http://www.finlex.fi/fi/laki/ajantasa/2013/20130497> (in Finnish)
<http://www.finlex.fi/sv/laki/ajantasa/2013/20130497> (in Swedish)
<http://www.finlex.fi/en/laki/kaannokset/2013/en20130497.pdf> (unofficial English translation)
- Government Decree on the Protection of Animals Used for Scientific or Educational Purposes (564/2013), available at:
<http://www.finlex.fi/fi/laki/alkup/2013/20130564> (in Finnish)
<http://www.finlex.fi/sv/laki/alkup/2013/20130564> (in Swedish)
<http://www.finlex.fi/en/laki/kaannokset/2013/20130564> (unofficial English translation)
- Governmental Decree on the Council on the Protection of Animals Used for Scientific or Educational Purposes (565/2013), available at:
<http://www.finlex.fi/fi/laki/alkup/2013/20130565> (in Finnish)
<http://www.finlex.fi/sv/laki/alkup/2013/20130565> (in Swedish)

3. Major changes introduced by the Directive 2010/63/EU in the project evaluation process

The Directive did not introduce major changes in the project evaluation process. The board pays now more attention to the severity classification according to the new legislation as well as the assessment of benefits and harms and their justified proportion, ensuring that the activities are according to the EU rules.

4. Regulation and authorisation process: main actors

4.1. Ministry: Ministry of Agriculture and Forestry (Department of Food and Health)

4.2. Competent authority: Ministry of Agriculture and Forestry (Department of Food and Health)

4.3. Entity responsible for the project authorisation: Project Authorisation Board (previously ELLA - Animal Experiment Board, created in 2006)

5. Project evaluation according to Article 38 of Directive 2010/63/EU

5.1. Geographical organization of the project evaluation process

The evaluation and authorisation is conducted at a national level by the Project Authorisation Board. This board is divided into 4 sections, which have their meetings in different cities. The applications (from any area of Finland) are primarily handled (evaluated and authorised) by the sections. Only in case of disagreement between the members of one section, the application is referred to the board meeting with all sections.

5.2. Evaluators

The evaluation is conducted by the national committee, the Project Authorisation Board, divided into 4 sections. The board is an independent authority working together with ESAVI (Regional State Administrative Agency for Southern Finland), where the 2 presenting officers of the board are placed. The presenting officers have a Ph.D. in biological sciences and are experts on animal experimentation. They prepare the applications to the board. Some minor

changes may also be granted by ESAVI, such as i) a short prolongation of the project period; ii) a minor increase on the number of animals used in the project; or iii) absolutely necessary and urgent changes that do not represent an increase in the classification of severity classification in the project authorisation.

5.2.1. Committee's composition

The national committee is composed by 18 members. The chairman and vice chairman must have a Master's degree in Law. The remaining members (16) must have recognized competence and experience in the use of animals in research, namely:

- 4 in scientific research,
- 4 in laboratory animal care/experimental techniques in animals,
- 4 in veterinary medicine,
- 4 in practical animal welfare or ethical issues (representing, for example, the biggest animal welfare organizations).

All these 16 members have substitute members, representing the same expertise as the ordinary member.

To summarize, committee consists in 1 chairman, 1 vice chairman, 16 ordinary members + 16 substitute members. Their identities and the meetings' dates are available at:

<http://www.laanhallitus.fi/lh%5Cetela%5Chankkeet%5Cellapro%5Chome.nsf/pages/BB14D517FF9A9564C225728A0047DA45?opendocument> .

These 16 members and their substitutes are divided into the 4 sections. Each section has 4 members + substitute members representing all the expertise mentioned previously. For example, in one section there are:

- 1 ordinary member + 1 substitute expert in scientific research,
- 1 ordinary member + 1 substitute expert in laboratory animal care/experimental techniques in animals,
- 1 ordinary member + 1 substitute expert in veterinary medicine,
- 1 ordinary member + 1 substitute expert in practical animal welfare or ethical issues.

The decisions can be made only when these 4 members or their substitutes attend the meetings.

The national chairman does not usually take part in the section meetings, although it is possible.

To summarize, in each section meeting there are 1-2 ELLA officers and 4 members or their substitutes, each one representing one of the expertise areas mentioned. The substitutes may attend the meetings without power of decision also when the member is participating.

5.3. Protocol submission

There are 2 forms: a standard form (available at:

[http://www.laanhallitus.fi/lh/etela/hankkeet/ellapro/home.nsf/files/Hankelupahakemus%20-%20EK%206/\\$file/Hankelupahakemus%20-%20EK%206.10.2014.docx](http://www.laanhallitus.fi/lh/etela/hankkeet/ellapro/home.nsf/files/Hankelupahakemus%20-%20EK%206/$file/Hankelupahakemus%20-%20EK%206.10.2014.docx)) and a simplified form for smaller projects

(available at: [http://www.laanhallitus.fi/lh/etela/hankkeet/ellapro/home.nsf/files/Hankehakemus%20-%20suppea%209/\\$file/Hankehakemus%20-%20suppea%209.7.2014.rtf](http://www.laanhallitus.fi/lh/etela/hankkeet/ellapro/home.nsf/files/Hankehakemus%20-%20suppea%209/$file/Hankehakemus%20-%20suppea%209.7.2014.rtf)).

Applications can be sent at any time to the presenting officers of the board. There are 1-2 section meetings a month.

The presenting officers receive the applications and contact the applicant if there is any information missing. They also ask for more detailed information and advice the applicant about the definitions of policy of the board. The applications are sent to the committee members one week before the meeting. After the meeting, if there are any questions, comments or information missing, the presenting officers contact the applicant, ask the information needed, forward the answers for the section members and act as a mediator when discussion between an applicant and section is needed.

5.4. Fees

In 2014 the applicants needed to pay 2500€ for very large application (used for a couple of times only), 1000€ for a normal application and 600€ for a simple project (only procedures with a minor severity and minor number of animals). Most of the licenses go to the group 1000€.

5.5. Guidelines for project evaluation

There are no specific guidelines for the committee on how to conduct the project evaluation. The consensus documents of EU Commission are used as guidelines.

5.6. Follow-up of projects' authorisation (I.e. inspections, retrospective review, etc.)

The animal welfare bodies and named persons in establishments are responsible to follow up the projects performed in their institutions.

The Regional State Administrative Agency (AVI) for Southern or Eastern Finland performs the inspections to assess compliance with the provisions of the Finnish Act on the Protection of Animals used for Scientific Purposes, and the terms and conditions of licenses, regarding establishments and projects.

Retrospective reviews will be done by Regional State Administrative Agency of Southern Finland, the presenting officers of project authorisation board. The board is informed about the results.

6. Changes expected to occur in 2015

There are no changes expected to occur in 2015 in the project evaluation process.